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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,127	04/08/2004	Michael D. Laufer	100873-266 (END6430USCNT4	8654

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EXAMINER	
WOO, JULIAN W	

ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
11/13/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary	Application No.	Applicant(s)	
	10/820,127	LAUFER ET AL.	
	Examiner	Art Unit	
	Julian W. Woo	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21 and 24-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21 and 24-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/6/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 25, 2008 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 26 and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not describe a corkscrew element or a suction device as part of first and second securing parts, which are parts of first and second members operatively linked by an actuating mechanism which facilitates simultaneous dependent movement of the first and second members.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-3, 5-7, 9, 17, 18, 20, 24, 25, 27-30, 45, and 49-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilk (5,395,367). Wilk discloses as claimed, at least in figure 7 and in col. 9, line 44 to col. 10, line 55; a tissue shaping instrument or apparatus including a proximal controlling portion (at the vicinity of 38) structured to actuate the tissue engaging devices (i.e., the controlling portion accommodates actuators for the devices), a distal effector portion (at the vicinity of 34, 35, and 36), an elongated member (32, 34b, 35b, or 36b), and a first tissue engaging device (e.g., 36) and a second tissue engaging device (e.g., 34) or means for transorally engaging a plurality of regions of stomach tissue with a plurality of members (e.g., 34, 36) from within the stomach and means for pulling tissue located between the plurality of regions of tissue prior to engaging the plurality of regions of tissue (e.g., 35), where the instrument is an endoscopic instrument, where the instrument includes a tissue securing device or a stapler (see col. 10, lines 31-35), where the first tissue engaging device (e.g., 36) includes a jawed clamp, where the second tissue engaging device comprises

opposed articulable arms (34a) with a tissue piercing element (pointed tips of 34a) disposed at a distal end of each arm, where the first tissue engaging device is non-piercing (e.g., 35), where at least a part of the elongated portion is flexible (e.g., at the springs with the spring-loaded pins, 38, or portions of shafts 34b, 35b, and/or 36b), where the instrument includes at least one working channel (within 32), where the plurality of members includes a first member (e.g., 36) having a first securing part (one jaw of 36a) configured to engage a first stomach tissue section and a second member (another jaw of 36a) having second securing part configured to engage a second stomach tissue section, where the means for engaging a plurality of stomach tissue regions includes an actuating mechanism (36c) operatively linking the first and second members to facilitate simultaneous movement of the members to draw together the first and second stomach tissue sections, where the first and second securing parts comprise tissue engaging means, where the engaging means includes a clamping device (e.g., 36), a suction device (not shown) disposed on a distal end of the articulable arm opposite the tissue piercing element (i.e., positioned adjacent the distal end of the articulable arm when shafts are in parallel) , or a grasping device (e.g., 35 or 36) or tissue grasper on a distal end of the articulable arm opposite the tissue piercing element (i.e., positioned adjacent the distal end of the articulable arm when shafts are in parallel), where the apparatus includes a means for securing the reconfigured tissue (e.g., a stapler or suture applicator), where the articulable arms of the second tissue engaging device are movable together relative to the first tissue engaging device, and

where the instrument includes first and second actuating mechanisms (e.g., 36C and 34C, respectively).

6. Claims 34, 35, 37, and 39-44 are rejected under 35 U.S.C. 102(e) as anticipated by Kuehn et al. (6,695,866). Kuehn et al. disclose, at least in figures 16, 17, and 19A-19D, an apparatus comprising a substantially rigid (i.e., somewhat flexible) elongated member (108) configured for transoral placement in the stomach, where the elongated member having a steerable distal region including first and second movable members (at 404) configured to be moved toward one another, and means for deploying an implant from at least one of the members (404), where the first movable member includes a first securing part (424) and the second movable member includes a second securing part (426), where the elongated member includes a clamping device or a grasping device (402), where the deploying means includes a distal end effector (402) configured to contact reconfigured stomach tissue, where the distal end effector includes a tissue fixation device (424, 426) configured for the application of a tissue fixation device, and where the apparatus includes means for controlling the distal end effector at a proximal end of the apparatus (432) and operatively connected to the distal end effector.

7. Claim 53 is rejected under 35 U.S.C. 102(b) as being anticipated by Kortenbach (6,086,600). Kortenbach discloses, at least in figures 1 and 11-16, an apparatus including a plurality of tissue engaging members having at least a first member (40) with a first securing part (57) configured to engage a first stomach tissue section and at least a second member (31) with a second securing part (46) configured to engage a second

stomach tissue section; and an actuating mechanism (108) operatively linking he first and second members to facilitate simultaneous dependent movement of the members, where the apparatus is configured for transorally engaging the plurality of regions of stomach tissues with the plurality of members, and where at least one of the members is configured to move toward another member.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.,* 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 4, 10-13, 21, and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk (5,395,367) in view of McGarry et al. (5,289,963). Wilk discloses the invention substantially as claimed. Wilk discloses a stapler as one of the tissue engaging devices or as a tissue securing device. However, Wilk does not disclose a tissue fixation device or a biocompatible, non-resorbable securing means that

is a staple and a stapler that is a one-sided stapler; nor does Wilk disclose that the instrument is sterilized. McGarry et al. teach, at least in figures 1 and 17-28 and in col. 10, lines 30-40 and col. 17, line 36 to col. 19, line 36; a tissue fixation device that is a biocompatible, non-resorbable securing means or a staple delivered from a one-sided stapler, where the stapler is sterilized. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of McGarry et al., to apply a one-sided stapler and a staple in the instrument of Wilk. Such devices would allow the endoscopic fastening of tissue, where the surgical site has narrow confines. It would also be obvious to sterilize the instrument, so that the instrument would not infect or contaminate the surgical site.

10. Claims 8, 26, 36, 38, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk (5,395,367) in view of McPherson et al. (5,437,266). Wilk discloses the invention substantially as claimed, where the apparatus includes an elongated member (32 and/or 34b, 35b, 36b) with a steerable distal region (at 34b, 35b, or 36b) and a means for deploying an implant (e.g., a stapler or suture applicator (not shown)), where the elongated member includes a suction device (not shown). However, Wilk does not disclose an engaging device or means that comprises a corkscrew-like retractor or a corkscrew element or an elongated member including the corkscrew element, nor does Wilk disclose tissue piercing elements at the distal end of the each of articulable arms (i.e., positioned adjacent to the distal ends of the arms), where the tissue piercing elements include a coil with a sharp distal tip. McPherson et al. teach a corkscrew-like retractor or a corkscrew element or a coil with sharp distal tip.

It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of McPherson et al., to apply a corkscrew-like retractor or a corkscrew element or a coil with a sharp distal tip in the instrument of Wilk. Such a device would allow the secure, endoscopic fastening of tissue being manipulated or retracted during a surgical procedure.

11. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk (5,395,367) in view of Kuehn et al. (6,695,866). Wilk discloses the invention substantially as claimed, but does not disclose a tissue fixation device that is a two-part fastener. Kuehn et al. teach, at least in figures 17 and 19A-19D, a tissue fixation device that is a two-part fastener (424, 426). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Kuehn et al., to apply a tissue fixation device that is a two-part fastener in the instrument of Wilk. Such a fastener would allow the secure fastening of tissue with little risk of separation of joined tissues.

12. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk (5,395,367) in view of Kammerer et al. (6,152,935). Wilk discloses the invention substantially as claimed, but does not disclose a tissue fixation device that is a suture or a T-bar suture. Kammerer et al. teach, at least in the figures, a suture or a T-bar suture (e.g., 30). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Kammerer et al., to apply a tissue fixation device that is a suture or a T-bar suture in the instrument of Wilk. Such a fastener

would allow the endoscopic fastening or approximation of tissues during a minimally-invasive surgical procedure.

13. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk (5,395,367) in view of Yoon (5,954,731). Wilk discloses the invention substantially as claimed, but does not disclose that instrument includes a viewing endoscope. Yoon teaches, at least in figure 4, an instrument with tissue engaging devices and a viewing endoscope (26). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Yoon, to include a viewing endoscope in the instrument of Wilk. Such a device would allow a surgeon to directly view a surgical site during a procedure and allow the surgeon to precisely manipulate the instrument within the surgical site.

14. Claims 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk (5,395,367) in view of Iacovelli (5,350,391). Wilk disclose the invention substantially as claimed, but does not disclose that the first actuating mechanism includes a control cable cooperating with a biasing member or a second actuating mechanism including a biasing member acting between the articulable arms and a pair of control cables cooperating with the biasing member. Iacovelli teaches, at least in figures 1-16 and col. 6, lines 42-64; an actuating mechanism for forceps or scissors, where the mechanism includes a biasing member (a torsion spring—not shown) acting between articulable arms (54) and cooperating with a pair of control cables (64). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Iacovelli, to include a biasing member and control cables with the

first and/or second actuating mechanisms of Wilk. A biasing member would urge the opening of the articulable arms, so that tissue or other objects may be grasped between the arms, while control cables would allow actuation of the arms via the narrow, endoscopic shaft of the instrument.

Response to Amendment

15. Applicant's arguments filed on August 25, 2008 have been fully considered but they are not persuasive. With respect to arguments regarding the rejections based on the Wilk reference: The first and second tissue engaging devices indeed are disposed on (i.e., positioned at and connected to) a distal effector portion of the elongated member, where elongated member 32 indeed has a proximal controlling portion and the distal effector portion—portions which accommodate and provide mechanical support for the actuators and effectors. Also, Wilk indeed discloses an actuating mechanism that operatively links first and second members (e.g., two elements 36a) and allows simultaneous dependent movement of the first and second members (i.e., simultaneous movement of both of the members depend upon movement of shaft 36b). With respect to arguments regarding the rejection of claims based on the Kuehn reference: Kuehn indeed discloses a substantially rigid catheter, where the modifier "substantially rigid" allows some flexibility (as Kuehn has disclosed), but also allows rigidity in that the catheter retains its tubular shape and length and a measure of stiffness. With respect to arguments regarding rejections based on Wilk in view of McGarry, McPherson, Kuehn, or Kammerer: McGarry, McPherson, Kuehn, and Kammerer teach tissue fixation devices, while Wilk provides the disclosure of an elongated member and actuating

mechanism as claimed. With respect to arguments regarding the rejection based on the Yoon reference: Yoon was relied upon solely for the teaching of an endoscope, while Wilk provides the disclosure of an elongated member and tissue engaging devices as claimed. With respect to arguments regarding the rejection based on the Iacovelli reference: Iacovelli was relied upon solely for the teaching of actuating mechanisms, while Wilk provides the disclosure of an elongated member and tissue engaging devices as claimed.

Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/
Primary Examiner, Art Unit 3773

November 6, 2008